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EXAMINER	
LAYNO, CARL HERNANDZ	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/017,998	Applicant(s) THONG ET AL.
	Examiner Carl H. Layno 1/27/04	Art Unit 3762

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,7*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Preliminary Amendment

1. Acknowledgment is made of applicant's preliminary amendment which was received by the Office on March 14, 2002. This document has been made of record in the file as Paper No.4.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file as Paper No.6.

Information Disclosure Statement

3. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on March 14, 2002 and on October 14, 2003. These documents have been made of record in the file as Paper Nos.5 and 7, respectively.

Drawings

4. Applicant's formal drawing has been approved by both the Examiner and the Draftsperson.

Claim Objections

5. Claims 33, 50, and 63 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Specifically, claim 33 is a repeat of claim 30, while claims 50 and 63 repeat verbatim the contents of claims 46 and 59, respectively.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1, the claim is incomplete and indefinite in that is unclear whether the applicant is intending to invoke the 112 6th paragraph "means" plus function language since the statement "a control means" (line 9) lacks a proper recitation of supporting function. In addition, the claim, as amended by the preliminary amendment, restates the element of a "defibrillator" (lines 4-6) in lines 7-9. To overcome this rejection, the Examiner recommends deleting this repeat language.

In regards to claims 2-4, as written, the claim language is indefinite in that the claim fails to recite positive structures to support the functional language in the claims regarding what the defibrillator and fibrillation detectors do.

Claims 5-69 are rejected since they depend from rejected base claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 2, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ujhelyi et al '621-A1 in view of Rosborough et al '267.

The Ujhelyi et al '621-A1 U.S Patent Application Publication describes an implantable cardioverter defibrillator (ICD) **103** (Fig.1 – p.2, paragraph [0023]) in communication with chambers of a patient's heart **105**. The device includes heart electrodes (not numbered), a fibrillation detector **104**, a defibrillation circuit **109**, sensors **107B**, and a microprocessor control circuit **106**. A patient activated control device (PAD) **110** communicates wirelessly with ICD **103** and permits the patient to control stimulation therapy through a keypad **118** and includes a button to deactivate atrial defibrillation (p.2, col.2, bottom of paragraph [0023]). The PAD is also equipped with a warning device **113** to alert the patient of anomalous monitored readings from ICD sensor(s) **107B** (p.3, col.1, paragraph [0026]). Unlike applicant's device, the Ujyhelyi et al publication does not specify what kind of sensors **107B** are.

The Rosborough et al '267 patent describes an implanted defibrillator (Fig.3) having heart sensing circuits **62,68**, defibrillation circuits **82,88,86**, a microprocessor **42**, and a hemodynamic sensor **86** for monitoring blood flow. Data from the hemodynamic sensor is used in conjunction with other heart sensors to determine the continued presence of a cardiac arrhythmia.

Lacking any criticality, to have selected the use of a hemodynamic sensor for sensor **107B** on the Ujhelyi et al ICD for sensing a pertinent cardiac parameter would have been an obvious substitution to one of ordinary skill since the monitoring of adequate blood flow from the heart is critical to the patient's well being and may be representative of a cardiac arrhythmia.

In regard to claim 2, applicant's attention is directed to Fig.2, which shows that the Ujhelyi et al device is intended to detect and treat of atrial fibrillations.

In regard to claims 13 and 14, applicant's attention is directed to p.2, col.2, paragraph [0023] bottom, which states that the patient activator device (PAD) includes an additional feature which permits the patient to cause an "immediate delivery of an electrical therapy". This would presumably involve an atrial defibrillation, since this is shown in Fig.2, blocks **204** thru **206**.

10. Claims 6, 7, 21, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ujhelyi et al '621-A1 in view of Rosborough et al '267 as applied to claims 1 and 2 above, and further in view of Elsberry et al '689.

The Elsberry et al '689 patent describes an implantable cardioverter defibrillator (ICD) which seeks to alleviate cardioversion shock pain prior to delivery to the patient by first applying electrical stimulation pulses to the nerves around the patient's spinal cord (i.e. spinal cord stimulation -- SCS) through the use of electrodes and a pulse generator **124,120** (Fig.4), and/or applying analgesic drugs, such as D-salotol or Quinidine (col.15, lines 11-28) from a drug pump **110** and drug chamber **114** (Fig.1) to reduce pain or induce sleep.

To have included pain reducing equipment, such as a spinal nerve stimulator and/or drug bolus and pump, on the modified implantable defibrillator of Ujhelyi et al would have been an

obvious modification to one of ordinary skill in view of the well known use of such pain reducing means in the art of ICDs for improved patient comfort during defibrillation treatments, as exemplified by the Elsberry et al '689 patent.

Allowable Subject Matter

11. Claims 3-5, 8-12, 18, 19, 22, 23, 25, 26, 32, 34-36, 38, 39, 41, 42, 44, 45, 50-59, and 64-69 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

12. Claims 15-17, 20, 27, 30, 31, 37, 40, 43, 47-49, and 60-62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Snyder et al '785 patent describes an external defibrillator (Fig.2) having most of applicant's claimed features including the elements of an audible warning indicator **26**, defibrillator output circuits **12,14**, a control means **20**, and data gathering sensors **28**, which may be a blood pressure detector or a hemodynamic monitor (col.9, lines 12-13). Unlike applicant's claimed device, it is unclear what kind of patient activated capabilities this defibrillator has.

The references of White '851 and Chen et al '617 describe atrial implantable defibrillators having patient controlled atrial shock capabilities. Unlike applicant's device, however, neither possesses detectors for sensing hemodynamic conditions.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed communications should be sent to the Office's new official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

Carl H. Layno

CARL LAYNO
PRIMARY EXAMINER

CHL
1/27/04